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JUN 12 2009

510(k) Summary

Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II)

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant	Twin Star Medical, Inc.
Submitter	Twin Star Medical, Inc. 1000 Westgate Drive, Suite 117 St. Paul, MN 55114 Tel: 612-990-0631 Fax: 651-209-0556
Contact Person	Jim Stice, President / CEO
Date Prepared	March 27, 2009
Device Trade Name	Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II)
Device Common Name	Monitor, Pressure, Intracompartmental
Classification Name	Unclassified, Product Code LXC
Classification Panel	Orthopedic
Predicate Devices	Twin Star Compartment Monitoring and Fluid Collection Catheter System (Catheter, K041771), Twin Star Compartment Pressure Monitoring and Fluid Collection Monitor (CMS Monitor, K060963), Synthes (USA) Compartmental Pressure Monitoring System (K031555), Stryker Compartment Syndrome Pressure Monitoring System (K844214).
Intended use	The Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II) is intended for the immediate or continuous measurement of intracompartmental pressures and/or the withdrawal of fluid for subsequent analysis. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome.
Device Description	The Twin Star Compartment Pressure Monitoring and Fluid Collection Catheter System (CMS-II) consists of four major components; an Introducer, a Pressure Monitoring and Fluid Collection (PMFC) Catheter, a Fluid Collection (FC) Catheter, and a Compartment Pressure Monitor. The Introducer consists of tear-away plastic sheath placed over a stainless steel trocar. The Introducer provides an access to the targeted muscle

	compartment to facilitate the placement of the indwelling Pressure Monitoring Fluid Collection / Fluid Collection catheter. The indwelling Catheter is designed to monitor intramuscular compartment pressure as well as provide a means to sample interstitial fluid for laboratory analysis. The indwelling Catheter is designed for use up to 24 hours. The Twin Star Compartment Pressure Monitoring provides a means of displaying the intracompartmental pressure.
Performance data	Bench testing was performed to support a determination of substantial equivalence and consisted of biocompatibility, electrical safety testing and design verification. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. A risk analysis of the system and its software was performed and testing was conducted to validate the systems overall operations.
Summary of Substantial Equivalence	The Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II) utilizes substantially equivalent performance attributes and safety components as the predicate devices. It shares the following similarities to the predicate devices: • Monitoring Pressure • Fluid Collection • Membrane Diameter • Single Patient Use • Pressure Sensor Location • Electrical Safety • Vacuum Source • Principles of operation
Conclusion	Based on the similar indications for use, technological characteristics and performance testing, Twin Star Medical, Inc. believes the proposed device, the Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II), is substantially equivalent to the Twin Star Compartment Monitoring and Fluid Collection Catheter System (Catheter, K041771), Twin Star Compartment Pressure Monitoring and Fluid Collection Monitor (CMS Monitor, K060963), Synthes (USA) Compartmental Pressure Monitoring System (K031555) and the Stryker Compartment Syndrome Pressure Monitoring System (K844214).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Twin Star Medical, Incorporated
% Sachs & Associates, Incorporated
Mr. Gregory W. Sachs
President
5116 Birch Road
Minnetonka, Minnesota 55345

JUN 12 2009

Re: K090961
Trade/Device Name: Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II)
Regulatory Class: II
Product Code: LXC
Dated: May 14, 2009
Received: May 15, 2009

Dear Mr. Sachs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K090961

Device Name: Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II)

Indications for Use:

The Twin Star Compartment Pressure Monitor and Fluid Collection Catheter System (CMS-II) is intended for the immediate or continuous measurement of intracompartmental pressures and/or the withdrawal of fluid for subsequent analysis. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090961